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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,004	10/21/2003	Ajitkumar B. Nair	1001.1696101	4874

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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,004	NAIR ET AL.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 35-57* is/are pending in the application.

4a) Of the above claim(s) *1-32 and 37-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33, 35, 36, 56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 12 December 2006.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 33, 36, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. (European Patent No. 0 200 668).

Fogarty et al. disclose a system comprising a device (Figure 2, elements 20 and 14) for trapping and removing an occlusive object (10) from a body passage (12). Fogarty et al. further disclose an elongated shaft (24) having a proximal section (not labeled) and a distal section (not labeled; end closer towards port 30), an inflation lumen (Figure 11, element 38) extending from the proximal section of the elongated shaft (24) to the distal section (see Figure 11) of the elongated shaft (24), a retrieval lumen (36) configured to receive at least part of the intravascular device (for example, portion 20; see Figure 6), and an expandable sleeve (Figure 3, element 16) disposed about the distal section of the elongated shaft (24) in fluid communication with the inflation lumen (via port 30). Figures 2-5 show the expandable sleeve (16) is configured to unfold distally and entirely intussuscept the intravascular device (14) in response to being inflated and Figure 2 shows the expandable sleeve (16) is configured to radially and

axially expand to a pre-defined shape (Fogarty et al. also disclose elastic or inelastic material may be used to form expandable sleeve 16; column 5, lines 33-37).

The preamble "A system for retrieving a blood clot disposed at a target site within a blood vessel" is given limited weight and the device disclosed by Fogarty et al. is capable of performing the function as claimed. Fogarty et al. disclose the device is used for retrieving a foreign object in a body passage. Therefore, the device disclosed by Fogarty et al. is capable of retrieving a blood clot (a foreign object) within a blood vessel (a body passage). Furthermore, the balloon catheter (comprised of elements 24, 36, 38, and 16) is configured to intussuscept the intravascular device (20/14) and blood clot (foreign object) while limiting the proximal flow of blood within the blood vessel (Figure 2 shows a seal between body passage 12 and the balloon catheter when sleeve 16 is inflated, thus being capable of limiting blood flow if body passage 12 is a blood vessel).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 35 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. in view of Hardwick (Patent No. 4,469,100).

Fogarty et al. disclose the device described above, wherein the expandable sleeve is configured to unfold distally (Figure 6 shows distal end "unfolds" when inflated as sleeve 16 engulfs foreign object 10). However, Fogarty et al. do not disclose an adhesive layer disposed about a portion of the elongated shaft. Like Fogarty et al., Hardwick disclose an intussuscepting balloon catheter (Figure 5). Unlike Fogarty et al., Hardwick teaches an elongated shaft (10) having an adhesive layer (column 4, lines 44-46) disposed about a portion of the shaft (at portions 17 and 19; see Figure 6) and proximal to a port (20; at portion 17), in order to bond or fuse the sleeve (16) to the elongated shaft (10), thus forming a closed balloon that can be inflated (column 4, lines 61-64). Therefore, to dispose an adhesive layer about a portion of the elongated shaft of the device of Fogarty et al. as taught by Hardwick would have been obvious to one of ordinary skill in the art at the time the invention was made in order to bond the sleeve to the elongated shaft, thus enabling inflation of the sleeve.

Response to Arguments

6. Applicant's arguments filed 12 December 2006 have been fully considered but they are not persuasive. Applicant argues primarily that each and every element of Applicant's amended claims are not present in the applied prior art references.

Regarding claim 33, Applicant argues that Fogarty et al. does not disclose an *expandable sleeve configured to unfold distally and intussuscept the intravascular*

device in response to being inflated. Examiner respectfully disagrees. Fogarty et al. disclose the step of inflating the expandable sleeve (column 7, lines13-15). When being inflated, the expandable sleeve (16) is *configured to* unfold distally (Figure 1 shows the sleeve in a folded configuration and Figure 2 shows the sleeve in an unfolded configuration) and when inflated (whether fully or partially), the expandable sleeve is *configured to* entirely intussuscept the intravascular device (Figures 2-4). Although Fogarty et al. disclose the extra step of pulling the catheter, the expandable sleeve is still inflated and is still *configured to* entirely intussuscept the intravascular device (Figures 2-4).

Regarding claim 35, Applicant argues that Hardwick discloses that the adhesive layer is simply located at the distal attachment point of the tubular balloon and that the balloon is not configured to unfold distally along an adhesive layer. However, Hardwick further discloses that the tubular balloon (or expandable sleeve, 16) is attached around the periphery of the catheter (or elongated shaft 10; column 4, lines 59-64), thus the adhesive (column 4, lines 42-49) forms an adhesive layer about *a portio*n (portions 17 and 19) of the elongated shaft. Furthermore, Figure 4 shows the balloon in a folded configuration (top layer is laying on top of the layer that is attached to the elongated shaft) and Figures 5-6 show the balloon unfolding distally along the adhesive layer (the top layer no longer lays on the layer attached to the shaft at portions 17 and 19, or any other portions of the shaft thereof).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
January 20, 2007

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
1/22/07